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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,042	04/21/2004	Trevor Barrowcliffe	674583-2001	7419

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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
04/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,042	BARROWCLIFFE, TREVOR	
	Examiner	Art Unit	
	AGNES B. ROOKE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *9-12,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 13-15, and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This FINAL office action is in response 01/07/2008.

Status of Claims

Claims 1-18 are pending. Claims 1-8, 13-15, and 18 are currently pending and under consideration. Claims 9-12 and 16-17 are withdrawn.

Rejection Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 13-15, and 18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al. (U.S. 5,506,112).

Lang et al. teach a method where a mixture of factor IXa, and phospholipids is added to a sample containing factor VIII, thus activating factor VIII to be assayed; and where subsequently activated factor VIII forms complex with factor IXa. See column 1, lines 8-14.

Applicants responded that in contrast to the instant invention, Lang et al. teach an assay method for determining the activity of factor VIII in a sample; where the reagent that is used to determine factor VIII activity comprises factor IX, factor X, calcium ions, thrombin, Phospholipids (column 1, lines 64-67); where the kit is also described (column 2, lines 28-34) as well as a method for measuring factor VIII activity

(see column 3, lines 1-9). Further, Applicants assert, that in contrast, pending claim 1 recites a kit comprising two pharmaceutical compositions, and that Lang et al. fail to teach any pharmaceutical compositions, let alone a kit comprising two pharmaceutical compositions, let alone a kit.

Examiner responds that Lang et al. teach a kit for measuring factor VIII activity and also teach a method where a mixture of factor IXa, and phospholipids is added to a sample containing factor VIII, thus activating factor VIII to be assayed. Therefore, Lang et al. teach a kit where a mixture of factor IXa (thus a pharmaceutical composition) is added to a sample containing factor VIII (thus a pharmaceutical composition).

Next, Applicants assert that Lang et al. do not teach a method of making pharmaceutical compositions.

Examiner responds that Lang et al. teach a process where a mixture of factor IXa (thus a pharmaceutical composition) is added to a sample containing factor VIII (thus a pharmaceutical composition).

Further, Applicants state that pending claims 13-15 relate to a method for potentiating factor VIII and that Lang et al. do not teach that.

Examiner responds that claims 13-15 relate to a method of potentating where factor IX and factor VIII are mixed together in a pharmaceutical composition. Thus, examiner concludes that mixing factor IXa (thus a pharmaceutical composition) with a sample containing factor VIII (thus a pharmaceutical composition) is clearly taught by Lang et al.

In addition, Applicants assert that the term "pharmaceutical composition" has a clear definition as being able to be administered to a human being.

Examiner agrees with the Applicants but also points out that a pharmaceutical carrier can be any buffer or water in a sample, for example.

Further, Applicants assert that assay methods and reagents used in assays are separate from pharmaceutical compositions and methods of potentating factor VIII.

Examiner responds that the claims are given the broadest reasonable interpretation and that the intended uses do not necessary carry any patentable weight in the invention being claimed.

Furthermore, Applicants assert that examiner is confusing the term "thus activating factor VIII to be assayed" and "potentiating factor VIII" as used in the pending claims. In addition, Applicants discussed the meaning of "enhancing" factor VIII in the presence of factor IX.

Examiner responds that those phrases are taken out of context of the claims, and that a method of "potentiating" in claim 13, represents an intended use only, and that the method has only one step of mixing factor IX and factor VIII. Therefore, this method is clearly anticipated by Lang et al. Also, examiner points out that two exact compositions when they are added or mixed together are expected to behave in the same manner, no matter how the method of mixing them is named.

Claims 4-8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Capon et al. (U.S. 4,965,199).

Capon et al. teach a method for producing factor VIII in recombinant mammalian host cell. See Abstract. Figure 1 teaches a step where factor IXa initiates the conversion of factor X to the activated form, factor Xa; where factor VIII is currently believed to function as a cofactor and is required to enhance the activity of factor IXa. This step in a cascade is critical, since two most common hemophilia disorders have been determined to be caused by the decreased functioning of either factor VIII (hemophilia A or classic hemophilia) or factor IXa (hemophilia B).

Therefore, factor VIII is capable of catalyzing the conversion of factor X to Xa in the presence of factor IXa as well as correcting the coagulation defect in plasma derived from hemophilia A affected individuals. See column 10, lines 27-32. Claim 8 is included in this rejection because it depends from rejected independent base claim 4.

Applicants assert that the examiner fails to consider the preamble of any of the claims in determining the scope of the claims i.e. that claims 4-8 relate to a method of treating hemophilia, and that nowhere in Capon is such a method of medical treatment described. Also, Applicants state that it is not possible to predict from this knowledge that factor IXa would potentiate the activity of low concentrations of factor VIII and that such finding was a surprise to those of skill in the art. In addition, Applicants assert that Figure 1 simply describes the activation of blood coagulation, and does not show any evidence that reductions in the amount of factor VIII can be utilized in the presence of factor IXa due to the potentiation of the factor VIII present.

Examiner responds that the phrase "treating of hemophilia" represents an intended use only, and also that the method claimed requires only one step of administering factor VIII and IXa. Capon teaches that factor VIII is capable of catalyzing the conversion of factor X to Xa in the presence of factor IXa, as well as correcting the coagulation defect in plasma derived from hemophilia A affected individuals. See column 10, lines 27-32. Also, Figure 1 of Capon shows that the surface-mediated activation of blood coagulation requires factor IXa and factor VIII. Therefore, factor VIII and factor IXa both take part in the cascade reaction of surface mediated activation of blood coagulation and the presence of coagulation factor IXa allows the concentration of coagulation factor VIII in the composition to be reduced in comparison to a composition which does not comprise a coagulation factor IXa (see the language claimed in the instant claim 4). Therefore, Capon teaches the method of treating hemophilia since the method claimed requires only the presence of factor VIII and factor IXa and the method claimed requires only one step. Further, examiner states that the presence of factor IXa will necessary potentiate the activity of low concentrations of factor VIII since this is an inherent characteristics of the interaction of factor IXa with factor VIII, for example. Therefore, the rejection is proper and is thus maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

/Karen Cochrane Carlson, Ph.D./

Primary Examiner, Art Unit 1656